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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/798,060               | 03/10/2004  | Alec Bobroff         | HM-04-PT-03-NP      | 5665             |
| 41883                    | 7590        | 01/08/2008           |                     |                  |
| HAEMONETICS CORPORATION  |             |                      | EXAMINER            |                  |
| 400 WOOD ROAD            |             |                      | HAND, MELANIE JO    |                  |
| BRAINTREE, MA 02184-9114 |             |                      | ART UNIT            | PAPER NUMBER     |
|                          |             |                      | 3761                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/798,060

Applicant(s)

BOBROFF ET AL.

Examiner

Melanie J. Hand

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed October 15, 2007 have been fully considered but they are not persuasive. Applicant argues that Inoue does not teach or suggest comparing historical data to current data. This limitation appears in newly presented claims 14 and 15. This is not found persuasive because Inoue teaches that memory 66 stores previously collected data (contrary to applicant's assertion that the system of Inoue does not keep previous data collected), which necessarily becomes historical data and new data points are collected. Inoue thus fairly suggests comparing the current procedure data to historical data, since both are available and can be displayed on display 12. Applicant further argues that each data point collected is "plugged into a formula...to generate the 'yet-to-be-collected amount'" and thus changing the frequency does not affect accuracy of the data presented to the user. The Office did not argue this. The Office is arguing that two data points do not always accurately show any fluctuation in data value therebetween that might be notable to the caregiver. Therefore smaller time intervals are more desirable than larger time intervals, as larger time intervals allow for more fluctuation in the data values that may be informative to the caregiver but are not recorded because they fall between time intervals. Thus the time interval between data points collected is a result effective variable, as it affects the accuracy (or better, reliability) of the data displayed, not of each data point received and stored.

### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. Claims 1-5, 7-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,153,828).

With respect to **claims 1-5 and 7-9**: Inoue et al. disclose a fluid monitoring and alert system 10 comprising a fluid collection device—having a drain tube 2, a vacuum reservoir 13, a suction pathway 41/others—vacuum pump (compressor) 17, sensors 40, 71, 73, a controller 18, an audible alarm 69, a visual display 12, and a valve 43 (whole document). The system records and displays data related to the system, including pressure data, via memory 66. The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68).

With respect to **claim 11**: It has been held that a recitation with respect to the manner in which a claimed invention is intended to be employed does not differentiate the claimed invention from a prior art satisfying the claimed structural limitations. *Ex parte Maham*, 2 USPQ2d 1647 (1987). *In re Paulsen*, 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994). Therefore, the system is considered capable of being used in the manner claimed.

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al ('828).

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With respect to **claim 12**: Inoue discloses that data, such as the amount of blood collected, is to be displayed on the visual display but does not expressly disclose the intervals at which this data is to be sampled or displayed. However, the interval at which the data is sampled affects the accuracy of the information displayed to the user. As such, the interval at which data is collected and/or displayed to the user is considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to have the display show data such as the volume of liquid collected in intervals of fifteen minutes, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to **claim 14**: Inoue does not teach that historical procedural data from a plurality of previous time intervals are displayed on the visual display along with the current procedure data. However since Inoue teaches memory 66 that stores data received from the at least one sensor and a visual display, it would be obvious to one of ordinary skill in the art to modify the device of Inoue such that the memory 66 and display 12 are operatively associated such that historical procedure data from a plurality of previous time intervals are displayed on the visual display along with the current procedure data with a reasonable expectation of success to provide additional information to the caregiver. (Col. 7, lines 6-10)

With respect to **claim 15**: Inoue discloses a fluid monitoring and alert system 10 comprising a fluid collection device having a vacuum reservoir 13 configured to be placed in communication with a suction pathway 41 that is at least partially defined by a surgical drain tube 2. At least one liquid collection sensor 40, 71, 73 configured to obtain data from the suction pathway. Controller 18 is connected to the at least one sensor 40, 71, 73 and inherently and necessarily has

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instructions to receive current procedure data from the sensor. The system records (saves) and displays data related to the system, including pressure data, via memory 66. Thus since the system stores and saves data, the system inherently and necessarily saves the data already received to create historical procedure data. The system has an audible alarm 69 that is activated when blood leakage is detected, an event that constitutes a predefined trend in the data of unexpected decrease in expected predefined blood volumes at certain time intervals.

The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68).

Inoue does not teach that the controller compares the current procedure data to the historical procedure data stored in memory 66. However, since Inoue teaches memory 66 that stores data received from the at least one sensor, it would be obvious to one of ordinary skill in the art to modify the device of Inoue such that the controller can compare the current procedure data received with the historical procedure data already stored in memory 66 with a reasonable expectation of success to provide additional information to the caregiver via display 12. (Col. 7, lines 6-10)

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Killian et al. (US 5,876,387).

With respect to **claim 6**: Inoue discloses the claimed invention but does not expressly disclose that the vacuum reservoir is joined to a facility-wide source of suction. Killian teaches a suction system to be used in a medical facility comprising a vacuum chamber and pump. Killian teaches that the system is connected to a central suction facility in case of failure of the vacuum pump (column 1, lines 39-64). One would have been motivated to modify the system of Inoue et al. to have the vacuum reservoir connected to a central suction facility, as taught by Killian, since

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doing so would allow for a replacement source of suction in the event of failure of the vacuum pump. Thus, it would have been obvious to one of ordinary skill in the art to modify the device of Inoue so as to have the vacuum reservoir connected to a facility-wide source of suction, as taught by Killian, since doing so would allow for a replacement source of suction in the event of failure of the vacuum pump.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Valerio et al. (US 5,989,234).

With respect to **claim 10**: Inoue discloses the claimed invention but does not expressly disclose that the system comprises an autotransfusion device. Valerio discloses a system for draining and collecting fluid from a body cavity comprising a vacuum pump and chamber. Valerio discloses that the device can be modified to serve as an autotransfusion device since reinfusing the patient's own blood is advantageous given today's concerns with communicable diseases (column 17, lines 22-29). (Also see Blankenship et al. US 5,116,312, column 1, lines 28-43). Thus, it would have been obvious to one of ordinary skill in the art to modify the system of Inoue to comprise an autotransfusion device, as taught by Valerio, since doing so would provide the additional advantages of transfusion a patient with their own blood, or other bodily fluid.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

December 30, 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

